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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUNDERS, DAVID A

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,931	<b>Applicant(s)</b> WILSON, ROSS PHILLIP	
	<b>Examiner</b> David A. Saunders	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,33-38,49-51,55-61 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) 55-61 and 67-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,33-38 and 49-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/06,10/19/06</u> .                                        | 6) <input type="checkbox"/> Other: _____                          |

### **AMENDMENT ENTRY**

Claims 1-7, 33-38, 49-51, 55-61 and 67-70 are pending, as presented in the amendment of 8/18/06.

### **RESPONSE TO ELECTION/RESTRICTION**

Applicant's election of Group I (claims 1-7, 33-38 and 49-51) in the reply filed on 3/3/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, concerning Groups I and II, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of *E. coli* as the species of claim 49 is acknowledged. Dependent claims 50-51 read on this species. The search has been extended to other species.

Claims 1-7, 33-38 and 49-51 are under examination.

### **OBJECTION(S) TO DISCLOSURE**

The amendment filed 8/18/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The incorporation by reference of Australian Application No. 2004900805 is improper, since it was not incorporated by reference at the International Stage.

Applicant is required to cancel the new matter in the reply to this Office Action.

### **OBJECTION(S) TO CLAIMS**

Claims 1 and 7 are objected to because of the following informalities: In claim 1, step (II) is further indented than the other steps. In claim 7, steps c)-d) and f)-h) are further indented than the other steps. Appropriate correction is required.

### **REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claims 1-7, 33-38 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step (I), recitation of both “having a blood group compatible” and “having an unmatched blood group” is confusing. If a donor and recipient are “compatible” then they do not have “an unmatched blood group”. Conversely, if a donor and recipient have “an unmatched blood group”, then they are not “compatible”.

In claims 2-6 “the canine animal” is unclear, because one does not know if this is the “donor canine animal” or the “recipient canine animal” of claim 1, step (I). It is believed that the disclosure teaches that the “donor canine animal” is intended.

In claim 7, one does not know how steps a)-h) fit into steps (I)-(III) of base claim 1. For example, does step c) of claim 7 correspond to step (II) of claim 1?

In claim 33, step (1), recitation of both “having a blood group compatible” and “having an unmatched blood group” is confusing, for the same reasons noted supra regarding claim 1.

In claims 34-39 “said canine animal” is unclear, because one does not know if this is the selected “canine animal” or the “recipient canine animal” of claim 33, step (1).

### **REJECTION(S) UNDER 35 USC 103**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natanson et al (Transfusion, 1993, cited in IDS of 8/18/06) in view of Giger et al (JAMVA, 1995, cited in IDS of 8/18/06).

Natanson et al teach experiments in which one conducts a plasma exchange in canines/dogs. Before the experiments, plasma preparations were obtained from nine animals by apheresis and then stored frozen (p 244, col. 2). In the subsequent experiments, in which six animals underwent plasma exchange, the animals were given their own plasma (p 244, col. 2). Natanson et al indicate that these three animals received their own (autologous) plasma, in order "to avoid incompatible reactions" (p 246, col. 2, 4<sup>th</sup>-5<sup>th</sup> lines from bottom). Thus Natanson et al would provide motivation for one to provide a compatible plasma, in the event that there might be no previously drawn autologous plasma.

Giger et al show that the major antigens that induce reactions of incompatibility, when blood products are transfused between dogs, are the DEA 1.1, DEA 1.2 and DEA 7 antigens (p 1360, col. 2). Hence it would have been obvious that, in the event that a dog should have need of a plasma transfusion, one would select a donor dog that would be negative for the DEA 1.1, DEA 1.2 and DEA 7 antigens, as in instant claims 2-7.

Claims 1, 7, 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Natanson et al (Transfusion, 1993, cited in IDS of 8/18/06) in view of both Giger et al (JAMVA, 1995, cited in IDS of 8/18/06) and Harvath et al (Infect & Immun., 1976, cited in IDS of 8/18/06).

Natanson et al and Giger et al have been cited supra against claim 1 for showing that one be motivated to provide a compatible plasma, when one is transfusing plasma between dogs. Harvath et al further show that one may want to transfuse a plasma from a donor immune dog to another dog, in order to provide the recipient dog with a passive humoral immunity. In so doing, one would have likewise been motivated to provide a

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donor dog that is compatible with the recipient dog, in order to avoid any of the “incompatible reactions” contemplated by Natanson et al.

Harvath et al et al teach the immunization of donor dogs; the initial and repeated immunizations correspond to steps (2)-(3) of instant claim 33; see p 1152, col. 1.

Harvath et al et al teach that one then obtains plasma from the immunized dogs by plasmapheresis; this step corresponds to step (4) of instant claim 33; see p 1152, col. 1.

Giger et al show that the major antigens that induce reactions of incompatibility, when blood products are transfused between dogs, are the DEA 1.1, DEA 1.2 and DEA 7 antigens (p 1360, col. 2). Hence it would have been obvious that, in the case in which one needs to provide a dog to donate an immune plasma preparation for transnsfusion, one would select a donor dog that would be negative for the DEA 1.1, DEA 1.2 and DEA 7 antigens, as in instant claims 34-37.

Regarding claim 7, the recited steps are those that one of ordinary skill would have recognized as being inherent and/or routine in conducting “repeated plasmapheresis”, as taught by Harvath et al at p 1152, col. 1.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Natanson et al (Transfusion, 1993) in view of both Giger et al (JAMVA, 1995) and Harvath et al (Infect & Immun., 1976), as applied to claim 33 above, and further in view of Emery et al (3,950,512, cited on PTO-892).

Emery et al show the further feature that numerous of the canine pathogens recited in claim 49 are of knowN interest for the immunization of dogs.

## **IDS NOT CONSIDERED**

The information disclosure statement filed 10/19/06 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the

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information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file. The reference referred to therein has been considered; however, the reference will not be listed in any issued US Patent.

**CONTACTS**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 5/19/09 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644